

# **FINANCIAL DISCLOSURE STATEMENT**

## **Applicability of 21 CFR Subchapter A; Part 54 – Financial Disclosure by Clinical Investigators**

Based upon review of the Agency Final rule; action on petition for reconsideration, we believe that financial disclosure by clinical investigators is applicable to this submission.

The financial disclosure rule is applicable to this submission due to the clinical data presented in support of this reclassification petition was collected under sponsored clinical trials. Financial disclosure was not obtained from the clinical investigators participating in the clinical trials conducted in Europe because the laws governing disclosure do not apply outside of the U.S.